General

Guideline Title

Magnesium sulphate for fetal neuroprotection.

Bibliographic Source(s)

Magee L, Sawchuck D, Synnes A, von Dadelszen P. Magnesium sulphate for fetal neuroprotection. J Obstet Gynaecol Can. 2011 May;33(5):516-29. [47 references] PubMed

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

The quality of evidence (I-III) and classification of recommendations (A-L) are defined at the end of the "Major Recommendations."

Magnesium Sulphate Use in Obstetrics

Summary Statement

1. "Imminent preterm birth" is defined as a high likelihood of birth due to one or both of the following conditions (II-2):
    - Active labour with ≥4 cm of cervical dilation, with or without preterm premature rupture of membranes (PPROM)
    - Planned preterm birth for fetal or maternal indications

Recommendations

1. For women with imminent preterm birth (≤31+6 weeks), antenatal magnesium sulphate administration should be considered for fetal neuroprotection. (I-A)
2. Although there is controversy about upper gestational age, antenatal magnesium sulphate for fetal neuroprotection should be considered from viability to ≤31+6 weeks. (II-1B)
3. If antenatal magnesium sulphate has been started for fetal neuroprotection, tocolysis should be discontinued. (III-A)
4. Magnesium sulphate should be discontinued if delivery is no longer imminent or a maximum of 24 hours of therapy has been administered. (II-2B)
5. For women with imminent preterm birth, antenatal magnesium sulphate for fetal neuroprotection should be administered as a 4 g intravenous (IV) loading dose, over 30 minutes, followed by a 1 g/hr maintenance infusion until birth. (II-2B)
6. For planned preterm birth for fetal or maternal indications, magnesium sulphate should be started, ideally within 4 hours before birth, as a 4

g IV loading dose, over 30 minutes, followed by a 1 g/hr maintenance infusion until birth. (II-2B)
7. There is insufficient evidence that a repeat course of antenatal magnesium sulphate for fetal neuroprotection should be administered. (III-L)
8. Delivery should not be delayed in order to administer antenatal magnesium sulphate for fetal neuroprotection if there are maternal and/or fetal indications for emergency delivery. (III-E)
9. When magnesium sulphate is given for fetal neuroprotection, maternity care providers should use existing protocols to monitor women who are receiving magnesium sulphate for preeclampsia/eclampsia. (III-A)
10. Indications for fetal heart rate monitoring in women receiving antenatal magnesium sulphate for neuroprotection should follow the fetal surveillance recommendations of the Society of Obstetricians and Gynecologists of Canada's 2007 Fetal Health Surveillance: Antepartum and Intrapartum Consensus Guideline. (III-A)
11. Since magnesium sulphate has the potential to alter the neonate's neurological evaluation, causing hypotonia or apnea, health care providers caring for the neonate should have an increased awareness of this effect. (III-C)

Definitions:

Quality of Evidence Assessment*

I: Evidence obtained from at least one properly randomized controlled trial.

II-1: Evidence from well-designed controlled trials without randomization.

II-2: Evidence from well-designed cohort (prospective or retrospective) or case–control studies, preferably from more than one centre or research group.

II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

*Adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.

Classification of Recommendations†

A. There is good evidence to recommend the clinical preventive action.

B. There is fair evidence to recommend the clinical preventive action.

C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making.

D. There is fair evidence to recommend against the clinical preventive action.

E. There is good evidence to recommend against the clinical preventive action.

L. There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making.

†Adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.

Clinical Algorithm(s)

The original guideline document contains an algorithm for magnesium sulphate for fetal neuroprotection in imminent preterm birth (≤31+6 weeks).

Scope

Disease/Condition(s)

- Preterm birth
- Cerebral palsy
- Neurological impairment

Guideline Category

Assessment of Therapeutic Effectiveness

Prevention

Risk Assessment

Treatment

Clinical Specialty

Neurology

Obstetrics and Gynecology

Pediatrics

Preventive Medicine

Intended Users

Advanced Practice Nurses

Physicians

Guideline Objective(s)

To provide guidelines for the use of antenatal magnesium sulphate for fetal neuroprotection of the preterm infant

Target Population

Women with imminent preterm birth (≤31+6 weeks) and their fetuses

Note: "Imminent preterm birth" is defined as a high likelihood of birth due to one or both of the following conditions: (1) active labour with ≥4 cm of cervical dilation, with or without preterm premature rupture of membranes (PPROM) or (2) planned preterm birth for fetal or maternal indications.

Interventions and Practices Considered

1. Antenatal magnesium sulphate ($MgSO_4$) for fetal neuroprotection
2. Corticosteroids for fetal lung maturation
3. Monitoring maternal vital signs as per existing $MgSO_4$ protocols
4. Providing continuous fetal heart surveillance

Major Outcomes Considered

- Incidence of cerebral palsy
- Incidence of neonatal death
- Incidence of substantial gross motor dysfunction
- Adverse effects of magnesium sulphate

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Published literature was retrieved through searches of PubMed or Medline, CINAHL, and the Cochrane Library in May 2010, using appropriate controlled vocabulary and key words (magnesium sulphate, cerebral palsy, preterm birth). Results were restricted to systematic reviews, randomized controlled trials, and relevant observational studies. There were no date or language restrictions. Searches were updated on a regular basis and incorporated in the guideline to August 2010. Grey (unpublished) literature was identified through searching the websites of health technology assessment and health technology assessment-related agencies, clinical practice guideline collections, clinical trial registries, and national and international medical specialty societies.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence Assessment*

I: Evidence obtained from at least one properly randomized controlled trial.

II-1: Evidence from well-designed controlled trials without randomization.

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*Adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The quality of evidence was rated using the criteria described in the Report of the Canadian Task Force on Preventive Health Care (see the "Rating Scheme for the Strength of the Evidence" field).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Not stated

Rating Scheme for the Strength of the Recommendations

Classification of Recommendations†

A. There is good evidence to recommend the clinical preventive action.

B. There is fair evidence to recommend the clinical preventive action.

C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making.

D. There is fair evidence to recommend against the clinical preventive action.

E. There is good evidence to recommend against the clinical preventive action.

L. There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making.

†Adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.

Cost Analysis

There is no anticipated significant increase in health-related costs with antenatal magnesium sulphate ($MgSO_4$) for fetal neuroprotection, because women eligible to receive antenatal $MgSO_4$ will be judged to have imminent preterm birth.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

This clinical practice guideline has been prepared by the Guidelines Consensus Group, reviewed by the Maternal Fetal Medicine Committee, and approved by the Executive and Council of the Society of Obstetricians and Gynaecologists of Canada. This document has been reviewed by the Fetus and Newborn Committee of the Canadian Paediatric Society.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Antenatal magnesium sulphate for fetal neuroprotection reduces the risk of death, cerebral palsy, and substantial gross motor dysfunction.

Potential Harms

- Magnesium sulphate ($MgSO_4$) produces peripheral vasodilation when infused intravenously. In neuroprotective intent trials, dose-related effects were common, particularly flushing, problems at the injection site, sweating, and nausea and vomiting (see Table 7 in the original guideline document). Serious maternal side effects were uncommon, with only maternal hypotension and tachycardia reaching statistical significance. Few women discontinued $MgSO_4$ because of side effects.
- Maternal adverse effects from $MgSO_4$ are dose-related, with respiratory or cardiac arrest associated with levels in excess of 5 mmol/L. Levels of this magnitude are not anticipated when magnesium contraindications are observed but are more frequent when $MgSO_4$ is prepared in the delivery suite rather than by a central pharmacy.
- Antenatal $MgSO_4$ for fetal neuroprotection should be used with caution in women who have renal impairment, and serum magnesium levels should be monitored.

Contraindications

Contraindications

Contraindications to magnesium sulfate include presence of maternal hypersensitivity to the drug, hepatic coma, or myasthenia gravis, and those whose fetus is unlikely to benefit from potential neuroprotection (i.e., severe fetal malformations or chromosomal abnormalities).

Qualifying Statements

Qualifying Statements

This document reflects emerging clinical and scientific advances on the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Local institutions can dictate amendments to these opinions. They should be well documented if modified at the local level. None of these contents may be reproduced in any form without prior written permission of the Society of Obstetricians and Gynaecologists of Canada (SOGC).

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

Foreign Language Translations

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Timeliness

Identifying Information and Availability

Bibliographic Source(s)

Magee L, Sawchuck D, Synnes A, von Dadelszen P. Magnesium sulphate for fetal neuroprotection. J Obstet Gynaecol Can. 2011 May;33(5):516-29. [47 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 May

Guideline Developer(s)

Society of Obstetricians and Gynaecologists of Canada - Medical Specialty Society

Source(s) of Funding

Society of Obstetricians and Gynaecologists of Canada

Guideline Committee

Guidelines Consensus Group

Composition of Group That Authored the Guideline

Principal Authors: Laura Magee, MD, Vancouver BC; Diane Sawchuck, RN, PhD, Vancouver BC; Anne Synnes, MD, Vancouver BC; Peter

von Dadelszen, MBChB, Vancouver BC

Financial Disclosures/Conflicts of Interest

Disclosure statements have been received from all members of the committees.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the Society of Obstetricians and Gynaecologists of Canada Web site .

Print copies: Available from the Society of Obstetricians and Gynaecologists of Canada, La société des obstétriciens et gynécologues du Canada (SOGC) 780 promenade Echo Drive Ottawa, ON K1S 5R7 (Canada); Phone: 1-800-561-2416.

Availability of Companion Documents

In addition, a French language version of the original guideline document is available in Portable Document Format (PDF) from the Society of Obstetricians and Gynaecologists of Canada Web site .

Patient Resources

None available

NGC Status

The NCG summary was completed by ECRI Institute on September 29, 2011. The information was verified by the guideline developer on November 2, 2011. This summary was updated by ECRI Institute on July 12, 2013 following the U.S. Food and Drug Administration advisory on Magnesium Sulfate.

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